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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/097,023	06/12/1998	JILL MCFADDEN	290252021800	2472
28075	7590	11/16/2004	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	09/097,023	MCFADDEN ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58, 59 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 is/are rejected.
- 7) ☐ Claim(s) 51 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The amendment filed 5/10/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: fig. 5 shows new matter of a braid (210) that is spaced free from the inner and outer liners. Fig. 6 shows new matter of a coil (216) that is established in contact with an inner liner, but free from the outer liner.

Applicants are required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53, 54, 55, 56, 58, and 59 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 05-220225 in view of SAMSON (U. S. Patent No. 5,702,373). JP 05-220225 shows a knitted reinforcing metal member 35 with an inner liner and outer cover. Samson is relied upon for description of the JP 05-220225 document.

Claims 1-5, 13, 14, 18, 19, 20, 24-27, 31-33, 40, 41, 45, 46, 47, 50, 53-56, 58, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by LEONI (U. S. Patent No. 5,772,681). Leoni describes a catheter having a knitted reinforcing member of nitinol between an inner liner

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and outer cover that is generally not expandable in the section adjacent to the balloon section (1:13-15, 2:48-3:20, 4:10-20, 5:28-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK (US Patent No. 4,637,396) in view of COX (US Patent No. 5,257,974). Cook discloses a catheter section having an elongate knit tubular multifilament member 23 made of interlocking up and down loops having an inner liner 22 and outer cover 24 and radiopaque markers. (See figs. 2, 4; col. 1, lines 21-25, 44-51; col. 2, line 29 - col. 3, line 9). Cook discloses that the catheter section is made so that it only expands to a predetermined diameter. Cook does not describe what predetermined diameters are selected. Cox teaches a multi-layered catheter that is made for predetermined expansion of less than 2.7% so the catheter could be used safely in intravascular procedures. (col. 3, lines 27-36; col. 25, lines 28-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cox in the catheter of Cook in order to protect a patient during intravascular procedures.

Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK and COX as applied to claims 1, 13, 31, 38, and 40 above,

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and further in view of LEONI. Cook and Cox disclose the claimed invention except for using nitinol as the knitted layer. Leoni teaches using nitinol as the knitted layer to restrict expansion as a reinforcement layer (5:26-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Leoni in the device of Cook and Cox in order to make use of the well known properties of NiTi for use in a patient's vascular. See col. 5, lines 14-27. The use of stainless steel and platinum in medical devices to make use of their notoriously well-known properties would be obvious to the ordinary artisan and Applicants have not stated that they have achieved any unexpected results different from these materials well-known properties and usage.

Claims 6-12, 15, 21, 28-30, 34-39, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI and further in view of ANDERSEN et al. (U. S. Patent No. 5,674, 276). JP 05-220225 or Leoni disclose the claimed invention except for using multifilaments with first and second materials of a metal and a polymer. Andersen teaches using multifilaments with first and second materials of a metal and a polymer to give desired characteristics to the knitted material for making tubular medical devices where the tube has a knitted member between an inner liner and outer cover (1:50 - 2:46, 4:32-43, 6:5-43, 8:2-7). The tubular device, disclosed by Anderson, is made of a knitted member that generally does not expand, but rather experiences plastic deformation to increase its dimensions (3:19-21). Andersen also teaches the use of radiopaque material to aid in visualizing the device internally. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Andersen in the invention of JP 05-220225 or Leoni in order to tailor the tubular device with different properties to achieve different functions (6:54-58). The use of stainless

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steel and platinum in medical devices to make use of their notoriously well-known properties would be obvious to the ordinary artisan and Applicants have not stated that they have achieved any unexpected results different from these materials well-known properties and usage.

Claims 17, 22, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI as applied to claims 54, 1, and 58 respectively above, and further in view of JANG et al. (U. S. Patent No. 4,898,591). JP 05-220225 or LEONI disclose the claimed invention except for the materials of construction of the inner and outer liner and cover respectively. Jang teaches the use of polyethylene as an inner liner and outer cover of a reinforced catheter to provide desired mechanical properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of JP 05-220225 or Leoni in order to achieve the desired flexibility, torsion and column rigidity for the catheter.

Claims 17, 22, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK and COX as applied to claims 1, 54, and 58 respectively above, and further in view of JANG et al. (U. S. Patent No. 4,898,591). Cook and Cox disclose the claimed invention except for polyethylene inner and outer liner and cover. Jang teaches the use of polyethylene as an inner liner and outer cover of a reinforced catheter to provide desired mechanical properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of Cook and Cox in order to achieve the desired flexibility, torsion and column rigidity for the catheter.

Allowable Subject Matter

Claims 51 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Comments concerning Applicants' remarks

Applicant argues that the amendments to the drawings is not new matter and points to the specification at page 10, lines 1-10. The examiner has carefully reviewed this section and the rest of the specification, but has not found support for the drawing amendments. Nowhere in the specification as filed did the Applicant disclose a braid (210) that is spaced free from the inner and outer liners or a coil (216) that is established in contact with an inner liner, but free from the outer liner (Fig. 6). Applicant's disclosure of a braid "interposed between" a liner and cover is not a disclosure of spacing on both sides or spacing on one side with contact on the other.

Applicant's desire to not amend the claims to establish "generally not radially expandable" (as recited in the claims) as "does not increase in diameter more than about 5% when an outwardly directed force is applied to an inner surface of the knit member." (as described in the specification at page 8, lines 17-20) is noted. Applicant desire to not establish the claim with this degree of particularity and distinctness, but rather to have some latitude in the aptness of terms, even though the examiner finds that the claim language is not as precise as the examiner would desire in performing an examination of this application is Applicant's privilege. In view of Applicant's decision, and Applicant's lack of other descriptions in the specification to describe "generally not radially expandable" the examiner interprets "generally not radially

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expandable” as a broad statement of a property of the knit member that there is some resistance to expansion and that the description in the specification at page 8, lines 17-20 is not a definition of the phrase, but rather one possible embodiment of the knit member.

Applicants’ arguments regarding reading “knitted” to mean “woven or braided” are not convincing. The prior art (JP 05-220225, translation on PAIR) states that the intermediate layer 35 is knitted. Applicant’s reliance on the drawings to interpret the invention of the prior art in opposition to taking the plain meaning of the term “knitted” is a tortuous exercise that is inconclusive and clearly misleading. Applicant’s examination of sketchy figures to see what she wants to see even though the figures lack the appropriate details to accurately discern the elemental structure is in opposition to the plain meaning of the description in the prior art that the member 35 is knitted. The dictionary meaning of knitted clearly establishes that the prior art shows the claimed invention.

Applicant argues that the prior art does not show a member that is generally not radially expandable. The examiner disagrees because the knitted nature of the member would inherently make the member generally not radially expandable because there is resistance to the expansion of the member that must be overcome to expand the member.

Applicants state that Leoni does not show a knit member generally not radially expandable. The examiner disagrees and refers to claim 9 where Leoni establishes the middle section to have an expandable section (i.e., the expandable part of the balloon) and a non-expandable section. Applicant’s arguments that knitted does not mean knitted are not convincing in view of the plain meaning of the term and the dictionary definition (see Applicant’s remarks

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page 13, first full paragraph). The up and down loops of the knitted member is inherent in view of the dictionary definition of knitted.

Applicant argues that Cox and Cook are not analogous art and that there is no motivation to combine the references. The examiner disagrees because the references are concerned with problems of medical reinforced tubular structures as well as analogous Patent Office classification. The motivation to combine the references is given above with respect to safe intravascular procedures.

Applicant's argument that the knit member of Cook used differently than the knit member of the present application is not convincing to withdraw the rejection above. Applicant's discovery of a new use of an old device does not carry patentable weight. The limitations recited in the claims read on the prior art.

Applicant argues that Cook teaches away from Cox and points to Cook's description motivating one of ordinary skill in the art to modify the invention of Cox to the Applicant's invention. Applicant's characterization of this teaching as "teaching away" is not correct because this teaching is actually the motivation to make the modification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
15 November 2004


MICHAEL J. HAYES
PRIMARY EXAMINER